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EXAMINER

PIERRE, JESSICA M

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,713

Applicant(s)

DIANA, RICHARD

Examiner

Pierre Jessica

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/14/04, 12/15/05, 5/22/06

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: On page 19 in line 5, "place" should be changed to "placed" in "is place proximally about the user's lower thigh 36. In line 11 of page 19, "preferably" should be "preferable" in "it may be preferably to pressurize the pads one at a time." On page 23 in line 13, the word "to" should be inserted after "adjacent" in "the relatively soft liner 250 is adjacent the user's foot."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable by JOHNSON ET AL (U.S. Pat. 5,314,455) in view of MASON ET AL (U.S. Pat. 5,080,089).

Regarding claim 1, JOHNSON ET AL teaches a pad system comprising a bladder with a fluid-filled chamber that has a distal portion and a proximal portion. A flexible liner (46) is wrapped about the bladder, forming compressible channels as

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shown in Figure 5. A binder (56), (20), and (22), is adapted to wrap about the flexible liner.

MASON ET AL teaches a bladder for containing a fluid that has ports for receiving fluid into the bladder and ports for withdrawing fluid from the bladder, with the inlet port being at the proximal portion and the outlet port being at the distal portion of the bladder. MASON ET AL also teaches a pump that has fluid communication with a fluid reservoir through a fluid directional system comprising a system of plumbing lines and valves. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the bladder by JOHNSON ET AL to include a pump as taught by MASON ET AL, including an inlet port to the distal portion and the outlet port to the proximal portion in order to circulate the fluid to provide a more continuous application of thermal therapy.

With regard to claim 4, JOHNSON ET AL teaches the system of claim 1 in view of MASON ET AL, wherein MASON ET AL teaches a therapeutic treatment device for heating or cooling the treatment region of the body with non-ambient temperature fluid. A valve (20) is used to regulate the temperature of the fluid in the system.

Regarding claim 5, MASON ET AL teaches spot welds (57) for blocking flow and restricting flow within the bladder.

Regarding claim 6, the combination of perimeter seal lines and spot welds are oriented in the longitudinal direction of the leg, which is also in the direction of the user's lymph flow.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,080,089).

Regarding claim 14, JOHNSON ET AL teaches the system of claim 1 in view of MASON ET AL, wherein MASON ET AL teaches a therapeutic apparatus that includes a bladder that has a plurality of separate compartments, with each compartment having its own ports which allow for fluids to be maintained separately within the compartments under different conditions. MASON ET AL also teaches a pump that feeds fluid under pressure into each of the ports of the bladder.

Claims 2 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable by JOHNSON ET AL in view of MASON ET AL as applied to claim 14 above, and further in view of MARBLE (U.S. Pat. 5,718,669).

Regarding claim 2, JOHNSON ET AL teaches the system of claim 1 in view of MASON ET AL, and MARBLE teaches a foam liner filled with foam pieces. However, it would have been obvious to one having ordinary skill in the art at time the invention was made to modify the invention by MARBLE by replacing the foam with a plurality of foam pieces in order to make the liner more comfortable, resilient, and accommodating to the complicated anatomical geometry of the user's limbs.

Claims 1, 4, 7-11, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of COPELAND ET AL (U.S. Pat. 4,149,529).

With regard to claims 1, 7-11, and 16, JOHNSON ET AL teaches the thermal therapeutic pad as recited in claim 1, wherein COPELAND ET AL teaches a circulation

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system for providing a continuous flow of fluid at a desired temperature including a heat exchanger (42). COPELAND ET AL shows a cooling system but also teaches an embodiment for heating the fluid in column 8, lines 39-46.

Regarding claim 16, JOHNSON ET AL teaches the system of claim 10 in view of MASON ET AL and COPELAND ET AL, wherein COPELAND ET AL teaches a control station that is disposed in a console. COPELAND ET AL does not teach a portable power supply disposed in a console; however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention by COPELAND ET AL by placing the power supply in a console in order to improve the performance of the therapeutic apparatus.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,080,089) as applied to claim 16 above, and further in view of RUSCIGNO (U.S. Pat. 4,552,132).

Regarding claim 12, JOHNSON ET AL teaches the system of claim 1 in view of MASON ET AL and RUSCIGNO, wherein RUSCIGNO teaches pulsating therapy system that includes a control unit with a motor-driven pump that sends continuous pressurized water flow into the tubular lead into the inlet port of the system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the invention by JOHNSON ET AL to pulse the fluid pressure to induce muscle relaxation.

Regarding claim 13, JOHNSON ET AL teaches the system of claim 12 in view of MASON ET AL and RUSCIGNO, wherein it would be an obvious matter of choice to

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make the pulsed fluid flow have a duration approximately equal to the transit time for the fluid through the bladder.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL as applied to claim 13 above, and further in view of GOLDSMITH (U.S. Pat. 5,047,421).

Regarding claim 17, JOHNSON ET AL teaches the system of claim 1 in view of MASON ET AL in view of GOLDSMITH, wherein GOLDSMITH teaches a brace that comprises a thermal bladder filled with a fluid made up of a mixture of water and isopropyl alcohol. Therefore, the invention by GOLDSMITH comprehends a fluid comprising a mixture of about 80% by volume of deionized distilled water and about 20% by volume of isopropyl alcohol. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify JOHNSON ET AL to include isopropyl alcohol to improve thermal transfer.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,080,089) as applied to claim 17 above, and further in view of MASON ET AL (U.S. Pat. 5,507,792).

With regard to claim 18, JOHNSON ET AL teaches the system of claim 1 in view of MASON ET AL ('089), wherein MASON ET AL ('792) teaches a therapeutic treatment device that substantially covers the shoulder of a user in column 8, lines 39-43. MASON ET AL ('792) also flow deflecting seal lines (58). It would have been obvious to further modify JOHNSON ET AL for use on the shoulder as taught by MASON ET AL

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('792) and to include seal lines as taught by MASON ET AL ('792) for improving temperature distributions.

Regarding claim 19, JOHNSON ET AL teaches the system of claim 18 in view of MASON ET AL. MASON ET AL ('089) already teaches a plurality of separate bladders in column 2, lines 25-29. It would have been obvious to further modify JOHNSON ET AL to use a plurality of individual bladders as taught by MASON ('089) to maintain different areas under different conditions.

Claims 20- 21 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,080,089) and MARBLE (U.S. Pat. 5,718,669).

Regarding claims 20 and 32, JOHNSON ET AL teaches a pad system comprising a pad with a fluid-filled chamber that has a distal portion and a proximal portion. MASON ET AL teaches a bladder for containing a fluid that has ports for receiving fluid into the bladder and ports for withdrawing fluid from the bladder, with the inlet port being at the proximal portion and the outlet port being at the distal portion of the bladder. MASON ET AL also teaches a pump that has fluid communication with a fluid reservoir through a fluid directional system comprising a system of plumbing lines and valves. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the bladder by JOHNSON ET AL to include the pump taught by MASON ET AL into the pad system by JOHNSON ET AL in order to effectively circulate fluid through the bladder to maintain a desired temperature. MASON ET AL teaches a liner material that covers the bladder portion, and MARBLE

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teaches a liner composed of foam pieces. It would have been obvious to one having ordinary skill in the art at time the invention was made to modify the invention by MARBLE by using a liner with foam pieces in order to make the liner more comfortable, resilient, and accommodating to the complicated anatomical geometry of the user's limbs.

Regarding claim 21, JOHNSON ET AL teaches the therapeutic pad system of claim 20 in view of MASON ET AL and MARBLE, wherein MASON ET AL teaches a pliable cushioning material that is wrapped about the bladder in order to insulate the bladder during use.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,080,089) as applied to claim 21 above, and further in view of MASON ET AL (U.S. Pat. 5,507,792).

Regarding claim 22, JOHNSON ET AL teaches the therapeutic pad system of claim 20 in view of MASON ET AL, wherein MASON ET AL (U.S. Pat. 5,507,792) teaches a bladder that is adapted to conform to various skin surfaces of the body, including a surface such as the ankle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify JOHNSON ET AL for use on the ankle as taught by MASON ET AL ('792) for a different part of the body.

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,080,089) as applied to claim 20 above, and further in view of COPELAND ET AL (U.S. Pat. 4,149,529).

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With regard to claims 23-30, JOHNSON ET AL teaches the system of claim 23 in view of MASON ET AL and COPELAND ET AL, wherein COPELAND ET AL teaches a control station for a therapy device that controls the temperature of the fluid that is delivered to a portion of the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention by JOHNSON ET AL by including the control station taught by COPELAND ET AL in order to improve the regulation and performance of the device.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL in view of MASON ET AL (U.S. Pat. 5,507,792) as applied to claim 20 above, and further in view of RUSCIGNO (U.S. Pat. 4,552,132).

Regarding claim 31, JOHNSON ET AL teaches the system of claim 20 in view of MASON ET AL and RUSCIGNO, wherein RUSCIGNO teaches pulsating therapy system that includes a control unit with a motor-driven pump that sends continuous pressurized water flow into the tubular lead into the inlet port of the system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention by JOHNSON ET AL by including the therapy system as taught by RUSCIGNO in order to improve the pressure flow of the water through the system.

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON ET AL as applied to claim 32 above, and further in view of MASON ET AL (U.S. Pat. 5,507,792).

Regarding claim 33, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the invention by JOHNSON ET AL to use the device on an ankle as taught by MASON ET AL ('792) to be able to use the device on other parts of the body.

Regarding claims 34-35, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the invention by JOHNSON ET AL to include seal lines to improve temperature distribution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Pierre whose telephone number is (571) 272-8920. The examiner can normally be reached on M-F, 7:00 am - 3:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Danton D. DeMille
Primary Examiner